

## REMARKS

### Remarks Regarding 35 U.S.C. §103(a) Rejections

In accordance with the Office Action, Claims 13-29 and 31 stand rejected under 35 U.S.C. §103(a) based on the Examiner's conclusion that such claims are unpatentable in light of United States Patent No. 6,747,917 to Jennings et al. (Jennings). Applicant submits that Jennings does not render each and every limitation of independent Claims 13, 21 and 27 obvious as it does not provide or suggest a teaching of every claim limitation. Furthermore, Jennings would not allow one skilled in the art to arrive at each and every limitation of independent Claims 13, 21 and 27 as Jennings teaches away from a number of the claimed features including, *inter alia*, the incorporation of differently shaped or sized beads within the same device and the removal of beads at the end of a woman's menstrual cycle. Additionally, the non-obvious nature of Applicant's invention is further demonstrated by secondary consideration evidence presented in the Declarations of Kelechi Agugo, Richard Cremins, Mary Finnegan, Gonzaga Lubega, and Dr. Robert Scanlon submitted herewith. For these reasons, Applicant traverses the Final Rejection and respectfully requests withdrawal of such rejection and allowance of Claims 13-29 and 31.

Jennings discloses a string of beads that includes one bead 102 of a first color representing the first day of menstrual bleeding, six beads 104 of a second color representing the early infertile days, twelve beads 106 of a third color representing fertile days, thirteen beads 108 of the second color representing later infertile days with one of the later infertile days beads 108 (the 27th bead 112 on the string) being provided in a fourth color that is different from the second color, and an optional thirty-third bead 110 signifying the end of the menstrual cycle. (See Figs. 1 and 2 and Col. 6, line 28 through Col. 8, line 59 of Jennings). Of note, the optional thirty-third bead 110 included in the loop 100 version of Jennings' device does not represent any of the days of the woman's menstrual cycle as Jennings' device is "suitable for use by women whose menstrual cycles last between 26 and 32 days" (Col. 7, lines 39-40) and such optional bead is not even included in the chain 200 version of Jennings' device (See Fig. 2).

As acknowledged by the Examiner on Page 4, paragraph 6 of the Office Action, Jennings fails to disclose "the different colors and/or shapes of the plurality of beads" of Applicant's invention. In this regard, Jennings specifically teaches that, "Preferably, beads 102, 104, 106, 108 are the same size and shape" (See Col. 7, lines 24-25, emphasis added). Moreover, when

viewed in the light of the Jennings disclosure in Col. 7, lines 24-25, it is clear that Jennings teaches away from the use of beads of varying sizes and shapes. The clear teaching of Jennings is that the use of uniform beads is preferable to varying sizes and shapes of beads. For at least this reason, one skilled in the art would not find it obvious to substitute beads of varying shapes and sizes for the uniformly shaped and sized beads of Jennings to arrive at the claimed limitations found in Claim 13.

While Jennings does mention that: “if the preferred shapes of beads are not locally available, other shapes can be used ... as long as a marker such as a ring is provided which can be moved from one bead to the next while remaining secure on the intended bead” (Col. 8, lines 4-9 with emphasis added), this does not amount to a teaching or suggestion that one of the thirty-two beads 102, 104, 106 or 108 representing days of the woman’s menstrual cycle may be shaped or sized differently from another one of the thirty-two beads 102, 104, 106 or 108. That is, no where does Jennings teach non-uniform bead sizes, but only that alternative shapes and sizes may be used so long as the beads on the device remain uniform on the device. Moreover, this statement comports with Jennings teachings that all beads be of uniform shape and size. While shapes other than the tear drop or oval shapes (the “preferred shapes”) taught in Jennings might be used, whatever shape is used, it is necessary that beads of the Jennings device be of uniform size and shape. In this regard, “the ring that is provided may be moved from one bead to the next while remaining secure on the intended bead” as taught in Col. 8, lines 7-9. The language that alternative shapes may be used merely implies that all of beads 102, 104, 106 and 108 may be shaped differently than the tear-dropped shaped beads 102, 104, 106 and 108 as shown in FIGS. 1, 1A, 1B and 2 of Jennings since, if one of beads 102, 104, 106 and 108 were too differently shaped or sized from the other of beads 102, 104, 106 and 108, then the ring would not be moveable from one bead to the other beads while remaining secure on all of the beads 102, 104, 106 and 108. In this regard, if the ring accidentally slips off a bead 102, 104, 106 or 108 or cannot be positioned on a bead 102, 104, 106 or 108 of Jennings’ device, the user will lose track of where they are in the menstrual cycle thereby defeating the usefulness of Jennings’ device and rendering Jennings’ device inoperable for its intended purpose.

Further still, while Jennings discloses that bead 110 may be smaller than the other beads on the device, this possibility does not render obvious the use of non-uniform beads of varying shapes and sizes obvious to represent menstrual cycle days. This is because bead 110 in

Jennings is used to indicate the end of the cycle as opposed to another day in the cycle. In this regard, bead 110 would not be required to retain the ring 114 as would every other bead that represented a day in the cycle. Moreover, it is noted that bead 110 is disclosed as being smaller than the other beads, yet could not be larger in that the ring 114 would still have to be capable of passing over the bead 110 in order for Jennings to function. Accordingly, while bead 110 is disclosed as being smaller than the other beads, this alone would not support a claim that it would be obvious to substitute beads of varying size and shape throughout the device in Jennings for representation of days in the menses cycle.

Furthermore, Jennings' mention that beads 102, 104, 106 and 108 may be consecutively numbered from 1 through 32 to provide "indicia other than color for indicating place in the cycle" (Col. 7, lines 52-55) does not amount to any teaching or suggestion that one or more of beads 102, 104, 106 and 108 are of two or more colors or a different size or shape than any other bead.

In contrast with Jennings, Claim 13 recites eight different beads. Of particular significance with respect to the disclosure of Jennings, Claim 13 specifically recites that the second beads are different in size than the first bead, that the third bead is of three colors and is differently sized than the second beads, that the fifth bead is of two colors, that the sixth beads are of two colors and are different in size than the fifth bead, and the eighth beads are shaped different from the seventh bead. Likewise, Claim 21 recites nine types of beads at least one of which is two or more colors and at least two of which are different in shape and/or size. Further, Claim 27 recites eight of beads that are different in appearance from one another in at least one of color, shape, and size. For at least these reasons, Claims 13, 21 and 27 are not made obvious by Jennings.

Furthermore, Claim 27 recites a type of bead associated with the day the woman's menstrual cycle crosses over to the fertile phase of her cycle (the "crossover bead"). The crossover bead is specifically recited as being a tri-color bead having three holes formed therethrough. The three holes allow the crossover bead to be positioned on the string in any one of three different orientations to provide an indication of an observation of the woman's cervical mucus made on such day. Jennings provides no bead that is suitable for this purpose. Jennings' beads are at most orientable in two orientations (forward facing and backward facing) as Jennings does not disclose the beads as having more than one hole formed therethrough. And,

once oriented, Jennings's beads cannot be reoriented in accordance with an observation of the woman's cervical mucus as Jennings teaches that they remain in a fixed position on the string. Further, Applicant respectfully submits that the Examiner's contention that there are two additional possible orientations (forward facing with the band element and backward facing with the band element), is not valid. This is because any such "orientation" would be lost once the band is moved to the next bead as required in order to use Jennings' device thereby resulting in a loss of the information regarding the observation of the woman's cervical mucus that is to be conveyed by any such "orientations". For at least this reason, Jennings does not render Claim 27 obvious.

Additionally, Claim 21 recites an ovulation prediction kit for determining the day during a fertile phase of the woman's menstrual cycle when a level of luteinizing hormone released by the woman's pituitary gland surges, such surge being correlated with the day of a cervical mucus peak in the woman's menstrual cycle. Claim 21 also recites a ninth type of bead positioned on the string to visually indicate the day of the cervical mucus peak in the woman's menstrual cycle when the luteinizing hormone level surges based on a result from the ovulation prediction kit and removed from the string at the end of the woman's menstrual cycle. There is a passing reference in the background section of Jennings to the existing use of urinary progesterone metabolite measurements. This disclosure is made in the background section with regard to alternative methods of monitoring a woman's menses cycle, but such brief mention does not amount to a teaching or suggestion of the combination of a bead device with an ovulation prediction kit providing such measurements. In fact, Jennings goes on to state that: "Despite these developments, there exists a need for alternative means for a woman to accurately predict her fertile window" (See Col. 2, lines 10-12, emphasis added). However, there is no mention anywhere in Jennings that Jennings' bead device be combined with an ovulation prediction kit providing such measurements, nor any reference to how such a combination would be made. Furthermore, Jennings does not disclose or suggest that any of the thirty-two beads 102, 104, 106 and 108 are positioned on the string of Jennings' device to provide a visual indication of the day of the woman's cervical mucus peak when the luteinizing hormone level surges based on a result from the ovulation prediction kit. It would not be obvious to one skilled in the art to combine Jennings with an ovulation prediction kit as claimed in Claim 21 because Jennings' entire disclosure is offered as an alternative to such an ovulation kit, not a supplementary tool to be

used in conjunction with such a kit.

Furthermore, Jennings specifically teaches, in the case of the loop form of Jennings' device (FIG. 1) that the ends of the string, cord or wire are "knotted or securely fastened to prevent tampering, such that the beads cannot be removed and the order of the beads is preserved. Preferably, bead 110 surrounds the knot or other fastening." (See Col. 6, lines 54-57, emphasis added). Also, Jennings specifically teaches, in the case of the open-end linear form of Jennings' device (FIG. 2), that the ends of the string, cord or wire be "securely knotted or otherwise fastened at both ends 202, 204 to prevent tampering, such that the beads cannot be removed from chain 200 and the order of the beads is preserved" (See Col. 8, lines 22-26, emphasis added). Thus, Jennings specifically teaches that the device is configured to prevent removal of the beads. This is in contrast with Applicant's invention as recited in Claims 13, 21 and 27 wherein all of the beads are removed each time the woman's menses phase concludes. Applicant's claimed invention is advantageous because it allows for positioning of the beads in desired numbers and orders to accommodate different menstrual cycles instead of moving a rubber band marker along a pre-configured set of beads each day as with the Jennings device (See Jennings, Col. 7, lines 26-38 and Col. 8, lines 35-46). This difference is particularly notable in that the pre-configured necklace or chain of Jennings may not be appropriate for use by women having menstrual cycles falling outside of regular 26 to 32 day cycles. In fact, Jennings specifically acknowledges this at Col. 7, lines 46-51 and Col. 8, lines 47-59. Further, since all beads are easily removed with Applicant's claimed apparatus, the beads are ready to be used again to provide indications for the woman's next menstrual cycle, but not necessarily in the same order as the previous month thereby accommodating variations in the woman's cycle from month to month. In this regard, it would not be obvious for one skilled in the art to modify Jennings to arrive at the removable bead feature recited in Claims 13, 21 and 27. Jennings is directed to device wherein the number of beads are fixed, thus limiting the use of the device in Jennings to women with regular cycles. Removal of the beads from Jennings device at the end of the woman's menstrual cycle would directly contradict the teachings of Jennings that the beads be prevented from being removed from the string. Thus, Jennings does not render Claims 13, 21 and 27 obvious because Jennings expressly teaches away from the removal of the beads as recited in Claims 13, 21 and 27.

In view of the noted deficiencies of Jennings as a reference, Jennings does not render Claims 13, 21 and 27 obvious in view of Jennings alone or in combination with other references. Since each of independent Claims 13, 21 and 27 are allowable, the respective claims depending therefrom which are allowable for at least the same reasons.

#### Secondary Consideration Evidence

In addition to the above reasons why Applicant's claimed invention is not obvious in view of Jennings, Applicant is submitting herewith several Declarations setting forth evidence of secondary considerations that rebut the Examiner's conclusion that Jennings renders Applicant's claimed invention obvious. The evidence set forth in the Declarations of Kelechi Agugo, Richard Cremins, Mary Finnegan, Gonzaga Lubega, and Dr. Robert Scanlon is specifically incorporated in this response.

As set forth in the Declarations of Kelechi Agugo, Richard Cremins and Gonzaga Lubega, Applicant's invention has enjoyed significant distribution and use in connection with fertility awareness and natural family planning efforts in Africa due to its claimed features that make it particularly suitable for women and couples of all educational backgrounds and literacy levels, women who are breast feeding, women who have irregular cycles, and women who have cycles outside of 26 to 32 days.

As set forth in the Declaration of Mary Finnegan and the Declaration of Dr. Robert Scanlon, Applicant's claimed invention also achieves various advantages which allow it to be used by all women, not just those with regular cycles, whereas the Jennings device has several drawbacks and disadvantages. As expressed by Mary Finnegan, an expert in the field of fertility awareness, and Dr. Robert Scanlon, a Doctor of Obstetrics and Gynecology and an expert in the field of fertility awareness, in view of these advantages and the unsuitability of the Jennings device for many women, no reasonable rationale exists for one skilled in the art of fertility awareness to modify the Jennings device to achieve Applicant's claimed invention.

In sum, the secondary consideration evidence demonstrates that those skilled in the art would not modify Jennings device to achieve Applicant's claimed invention.

Conclusion:

Based upon the foregoing, Applicant believes that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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Date: May 11, 2009

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